



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 16 1999

5 2 3 1 '99 JUL 20 P 1:37

Ms. Margaret J. Jack
Program Director
Hoffman-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Re: Docket Nos. 99P-1413/CP1 and 98N-0056

Dear Ms. Jack:

This letter responds to your citizen petition dated May 14, 1999, requesting that the Food and Drug Administration (FDA) add orlistat to the priority section of the List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (Docket No. 98N-0056). The Agency has evaluated your petition and concluded that orlistat meets the criteria for inclusion on the priority section of the list. Accordingly, your petition is granted. FDA will add orlistat to the priority section of the list for the indications obesity management and reduction of the risk of weight regain.

This addition is effective as of the date of this letter. If you submit a Proposed Pediatric Study Request before the list is physically updated, please include a copy of this letter with your proposal to ensure your proposal is reviewed in the proper order.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-1413

PAV 1

Consult:MHess(HFD-510):06/04/99
Drafted:LCusumano(HFD-7):06/14/99
Edited:SOMalley(HFD-7):06/15/99

cc:

HFD-1

HFD-2

HFA-305/99P-1413/ep1
/98N-0056

HFD-7

HFD-7/DRead

LCusumano

TBrice

HFD-7/C

HFD-7/R

GC-1/AWion

HFD-102

HFD-510

HFD-104

06/17
HFD-7 6/17/99

6/24/99
D. [Signature]

ED 7/2/99

Japela 7/7/99

J. Ward 7/16/99